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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,735	11/21/2003	Jonathan Samuel Minden	058432-5003US	3539

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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,735	MINDEN, JONATHAN SAMUEL	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *May 25, 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *10-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 25-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 6, 2006, is entered.

During a telephone interview on May 23, 2006, Applicant expressed his intention to submit a supplemental response containing additional claims. On May 25, 2006, Applicant faxed to Examiner an unofficial copy of said supplemental response.

At the time of drafting this Office Action, said supplemental response has not been displayed in the information file wrapper application history system (IFW). Examiner expects that the official supplemental response, identical to said unofficial copy, will be scanned and displayed in the information file wrapper application history system (IFW) shortly. However, due to administrative time constraints, the instant Office Action is based on Applicant's faxed unofficial copy of said supplemental response.

Currently, claims 1-9 and 25-37 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The disclosure is objected to because of the following informalities:

> Throughout the Specification, the recitation of "half life" of binding or "half life" of release is indefinite because it is not clear how one skilled in the art can make a capture device having a specific "half-life of binding" or a specific "half life of release" when the definitions of "half-life of binding" and the "half life of release" only take into account the parameter of time (i.e. the amount of time required to covalently bind or release half the protein), and do not take into account initial concentration of reactants as well as the forward and reverse rate constants.

Appropriate correction is required.

Claim Rejections - 35 USC § 112 – first paragraph

Claims 1-9 and 30-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention. Specifically, the specification does not enable one skilled in the art to make a capture device having a specific "half life of release."

Claim 1 recites a biomolecule capture device "having a half-life of release of desired biomolecules which are bound thereto of less than 1 hour." The specification defines the term "release half life" as the amount of time required to release half of the protein which is covalently bound (see Specification at p. 12, lines 8-10).

The definition of "release half life," as recited in the Specification, does not appear to take into account any reaction rate constants, initial concentration of biomolecules in the device's environment, the solubility of biomolecules in water, the surface area of the device, or the pH and buffer capacity of the device's environment.

According to Lodish et al., MOLECULAR CELL BIOLOGY, Section 2.3 (2000), the rate of a chemical reaction is affected by the initial concentration of reactants as well as the forward and reverse rate constants (see Equations 2-3, 2-4). Here, since the definition of "half life of release" only takes into account the parameter of time (i.e. the amount of time required to release half the protein), and does not take into account initial concentration of reactants as well as the forward and reverse rate constants, it is not clear how one skilled in the art can make a capture device having a specific "half life of release."

According to Heller *et al.*, 22 J. APP. POLYM. SCI. 1991 (1978), the rate of drug release from a maleic anhydride biomolecule capture device is determined by such factors as (1) solubility of the drug in water,

(2) total surface area of the device, and (3) the pH and buffer capacity of the device's environment. Here, since the definition of "half life of release" only takes into account the parameter of time (i.e. the amount of time required to release half the protein), and does not take into account such factors as (1) solubility of the drug in water, (2) total surface area of the device, and (3) the pH and buffer capacity of the device's environment, it is not clear how one skilled in the art can make a capture device having a specific "half life of release."

In the decision of *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), the factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Here, the Specification does not provide any direction or working examples relating to the measurement of "half life of release". Given Applicant's limited description of "half life of release," the quantity of experimentation needed to make a capture device having a specific "half life of release" is undue.

Claim Rejections - 35 USC § 112 – second paragraph

Claims 1-9 and 25-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-9 and 30-34, the recitation of "the maleic anhydride compound having a half life of release of desired biomolecules which are bound thereto of less than 1 hour" is indefinite. How one skilled in the art can make a capture device having a specific "half life of release" when the definition of "half life of release" only takes into account the parameter of time (i.e. the amount of time required to release half the protein) is not clear.

Claim Rejections - 35 USC § 102

Claims 1-3, 5-9, 25 and 27-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Schuck & Wildi (US 3,679,653).

Schuck & Wildi describe a biomolecule capture device (see Title, "Hormonally-active reaction product of a polymer with a hormone") comprising:

(a) a substrate having a surface (see Title, "polymer"); and

(b) a maleic anhydride compound covalently bound to the surface of the substrate (see col. 6, lines 19-28).

Notwithstanding the issue of indefiniteness, addressed supra, *Claim Rejections - 35 USC § 112 – second paragraph*, Examiner interprets the language "having a half life of release of desired biomolecules which are bound thereto of less than 1 hour" as a compound capable of "having a half life of release of desired biomolecules which are bound thereto of less than 1 hour".

Claim Rejections - 35 USC § 103

Claims 4 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schuck & Wildi (US 3,679,653) in view of Schmincke-Ott & Bisswanger, 10 Prep. Biochem. 69 (1980) (abstract only).

Schuck & Wildi describe a biomolecule capture device as substantially described, *supra*, and incorporated herein.

Schuck & Wildi do not describe a device incorporating "aminohexyl agarose" or "aminododecyl agarose".

However, Schmincke-Ott & Bisswanger describe the general use of aminohexylagarose for concentrating protein solutions (see Title).

It would have been obvious for a person of ordinary skill in the art to modify the biomolecule capture device of Schuck & Wildi to include aminohexylagarose because Schmincke-Ott & Bisswanger discovered that aminohexylagarose has "high capacity" for adsorbing different proteins "with practically no losses of material or activity" (see Abstract).

Response to Arguments

In prior Office Action, claims 1-4 and 7-9 were rejected under 35 U.S.C. 102(b) as being anticipated by Singh *et al.*, 203 ARCH. BIOCHEM. BIOPHYS. 774 (1980). In addition, claims 1-3, 5-9, 25 and 27-29 were rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al. (US 6,372,813). Finally, claim 5-6 and 25-29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Singh *et al.*, 203 ARCH. BIOCHEM. BIOPHYS. 774 (1980), in view of Kinsella & Shetty (US 4,348,479).

In response, Applicant amends independent claim 1 to delete the terms "biomolecule binding" and "half life of binding" (see Applicant's reply, filed February 6, 2006).

In Applicant's supplemental Reply (unofficial copy), faxed May 25, 2006, Applicant reiterates that Singh *et al.*, 203 ARCH. BIOCHEM. BIOPHYS. 774 (1980), describe a "maleimido" compound rather than the claimed maleic anhydride compound. Similarly, Applicant reiterates that Johnson *et al.* (US 6,372,813) also describes a "maleimido" compound rather than the claimed maleic anhydride compound. Applicant further adds that the compounds of Singh et al. and Johnson et al. have a different orientation, as compared to Applicant's invention, as depicted in Figs. 1 and 2. Finally, Applicant adds that the reaction mechanisms of Johnson et al. and Singh et al. are essentially irreversible, in contrast to Applicant's reversible mechanism.

Applicant's amendment and/or arguments are fully persuasive and sufficient to overcome these rejections. Accordingly, these rejections are withdrawn.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv

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